Core Components of Regulatory Science Curriculum

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Regulatory Science Training

Gaps and Opportunities:

- Lack of Regulatory Science Core Competencies to guide training and curriculum development*
  - Approaches to integrate RS into existing programs & develop new programs
  - Broader awareness to established researchers

- Training pathways can be opaque, with limited incentives at different stages in the career

- Opportunity to leverage network of institutions and PPPs

*Focus on competencies in part driven by gap identified by previous IOM workshop and prior work on Translational Research competencies

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Regulatory Science, Regulatory Affairs and Translational Science

The Intersection of Regulatory Science and Regulatory Affairs

Regulatory Science - the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA regulated products.

- Drives new research questions and approaches across the pathway.

▲ **Regulatory Affairs** - Process and checkpoints along pathway to ensure quality, safety, efficacy and overall compliance with current regulations.

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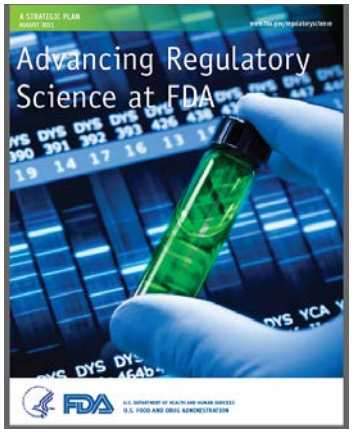
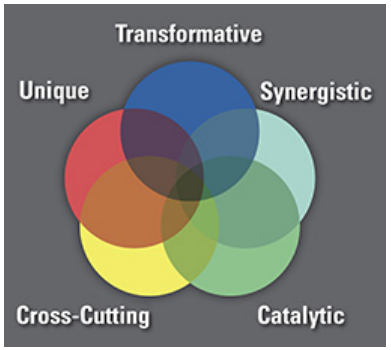
FDA Priorities and NIH - FDA Collaboration on Regulatory and Translational Science



NIH – FDA Joint Leadership Council – "help ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process"



Regulatory Science Awards (Common Fund)

- University of Michigan, Ann Arbor – Accelerating Drug and Device Evaluation through Innovative Clinical Trial Design
- Harvard University Medical School, Boston – Heart-Lung Micromachine for Safety and Efficacy Testing

FDA Centers of Excellence in Regulatory Science and Innovation

- Education, Research and Scientific Exchange

NIH
The Common Fund

FDA

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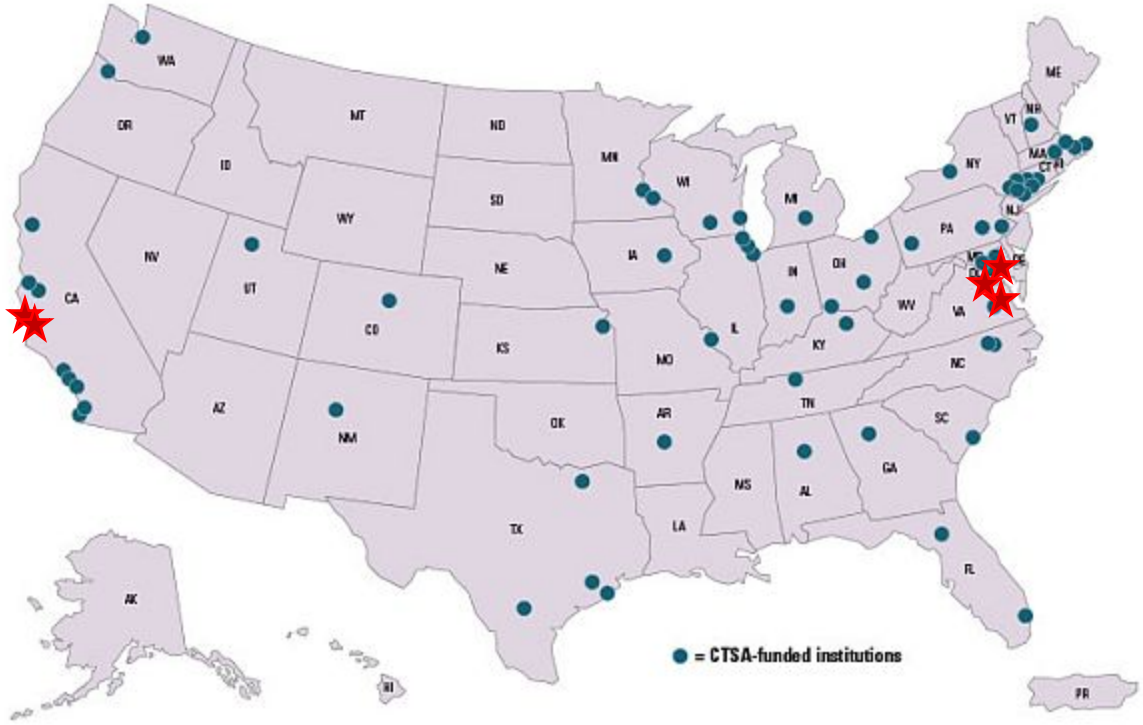
Regulatory Science and Translational Science



CERSI Institutions

https://ctsacentral.org/about-us/ctsa/

CTSAs and CERSIs have shared missions and both supporting research and education related to Regulatory Science. CTSAs provide significant network capacity to develop, demonstrate and disseminate Regulatory Science innovations in research and training

Collaborate to improve the efficiency and effectiveness of translational science and medical product development

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Regulatory Science Group

Regulatory Science Workgroup was originally initiated as a CTSA Consortium workgroup (while broader)

Goal: Promote and coordinate Regulatory Science education, training and research by sharing information, best practices, development of resources and supporting pilot projects

- 15 CTSAs, FDA CERSI's, FDA, NIH
- Several members recently developed or planning new RS MS and Certificate Programs

Developing Regulatory Science Competencies

- Proposed broad Core Thematic Areas and associated Competencies as a guide for Regulatory Science training, can be further refined as necessary for individual/program

- Additional feedback on the competencies from representatives from academia, government, industry, associations

- Survey as next phase to receive feedback and further harmonize the Competencies

Regulatory Science Competencies

- Envision trainees have existing training or active research programs in one of the following Key Technical/Priority Areas:
  - Epidemiology
  - Clinical Pharmacology/Pharmacokinetics
  - Toxicology
  - Bioengineering and Nano-engineering
  - Molecular Biology and Genetics/Personalized Medicine
  - Behavioral Sciences (and health literacy)
  - Tobacco (social, marketing/advertising, product qualification, health warnings)
  - Food Safety (prevention focused systems, planning and performance measures)
  - Medical Countermeasures Development
  - Product Manufacturing and Quality (identify counterfeit drugs, identify and reduce contamination, evaluate novel and improved manufacturing, analytical methods)

Core Thematic Area 1: Regulatory Science Research Questions and Priorities

	Competencies	% who Agree or Strongly Agree
1	Summarize current FDA Regulatory Science priorities	86
2	Identify additional Regulatory Science questions via gap analysis of translational research pathway, considering current evaluation and approval process of medical products	90
3	Critique Regulatory Science research questions and priorities	97
4	Identify approaches and techniques to address areas of Regulatory Science (outline a vision for a research program)	83
5	Work as a leader of a multidisciplinary team	79
6	Describe principles of Team Science, creating a network of individuals across FDA, NIH, CTSAs, professional societies, and industry	76

The five-point scale used for the survey was:

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

Regulatory Science Core Competencies & Curricular Guidelines Workshop

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Eleven Core Thematic Areas

1. Regulatory Science Research Questions and Priorities
2. Regulatory Policies and Process
3. Research Ethics
4. Drug Discovery and Development
5. Medical Device Innovation
6. Preclinical
7. Clinical Trials
8. Post-Marketing and Compliance
9. Analytical Approaches and Tools
10. Communication
11. Technology and Innovation

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Workshop Summary Paper

COMMENTARY

Advancing a Vision for Regulatory Science Training

Joan E. Adamo, Ph.D.[1], Erin E. Wilhelm, M.P.H.[2], and Scott J. Steele, Ph.D.[3]

Abstract
Regulatory science, a complex field which draws on science, law, and policy, is a growing discipline in medical-related applications. Competencies help define both a discipline and the criteria to measure high-quality learning experiences. This paper identifies competencies for regulatory science, how they were developed, and broader recommendations to enhance education and training in this burgeoning field, including a multifaceted training approach. Clin Trans Sci 2015; Volume #: 1–4

Keywords: regulatory science, translational science, training, competencies

DOI: 10.1111/cts.12298

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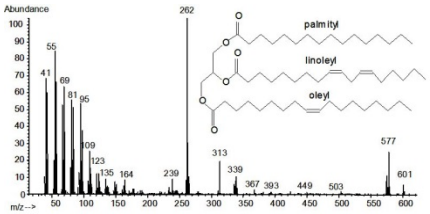
Tripartite Training for Regulatory Science

Academic Learning

Regulatory Experience

Industry Internship



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Recent Models of Formal Programs

- Georgetown University CERSI- Regulatory Science Concentration in MS in Clinical and Translational Research (CTSA program)

- M-CERSI MS in Regulatory Science On-line Program

- UPenn ITMAT- MS in Regulatory Science (separate MS in Regulatory Affairs)
    - Requires advanced degree

- UR Developing Certificate Program (compliment to advanced degree)
    - Linked with current Training Programs (TL1, KL2, BEST)

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Summary

- Disseminate and utilize Competencies to help guide training– as common template and planning tool
  - Integrating courses, case studies, workshops into existing programs (via concentration or certificate vs MS?)

- Integrate experiential Regulatory Science training opportunities across sectors—academia, industry and regulatory agencies

- Utilize consortium models to support training and research
  - leveraging complimentary programs, resources and expertise

- Address sustainability of programs and value of partnerships (FDA, NIH, Foundations, PPPs, patient groups)

- Needs assessment key gap (workforce & training)

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